

Claims

1. A freeze-dried formulation comprising follicle-stimulating hormone (FSH) or a variant thereof as well as luteinising hormone (LH) or a variant thereof, as well
5 as a surfactant selected from a polysorbate including Tween 20 (polyoxyethylene (20) sorbitan monolaurate), Tween 40 (polyoxyethylene (20) sorbitan monopalmitate), Tween 80 (polyoxyethylene (20) sorbitan monooleate).
2. The freeze dried formulation according to claim 1, wherein the surfactant is
10 Tween 20.
3. The freeze dried formulation according to any of claims 1 or 2, wherein the follicle-stimulating hormone is human follicle-stimulating hormone and/or the luteinising hormone (LH) is human luteinising hormone (LH).
4. The freeze dried formulation according to claim 3, wherein the
15 follicle-stimulating hormone is urinary human follicle-stimulating hormone and/or the luteinising hormone (LH) is urinary human luteinising hormone (LH).
5. The freeze dried formulation according to any of claims 1 to 3, wherein the follicle-stimulating hormone is recombinant human follicle-stimulating hormone and/or the luteinising hormone (LH) is recombinant human luteinising hormone
20 (LH).
6. The freeze dried formulation according to any of the preceding claims, wherein the follicle-stimulating hormone (FSH) is present at a concentration (w/w) of at or about 0.1 to 10 µg/mg of the total formulation.
7. The freeze dried formulation according to claim 6, wherein the
25 follicle-stimulating hormone (FSH) is present at a concentration of at or about 0.3 to 5 µg/mg of the total formulation.
8. The freeze dried formulation according to claim 7, wherein the follicle-stimulating hormone (FSH) is present at a concentration of at or about 0.37 to 2 µg/mg of the total formulation.

9. The freeze dried formulation according to any of the preceding claims, wherein the luteinising hormone (LH) is present at a concentration of at or about 0.1 to 3 µg/mg of the total formulation.
- 5 10. The freeze dried formulation according to claim 9, wherein the luteinising hormone (LH) is present at a concentration of at or about 0.1 to 1 µg/mg of the total formulation.
11. The freeze dried formulation according to claim 10, wherein the luteinising hormone (LH) is present at a concentration of at or about 0.1 to 0.6 µg/mg of the total formulation.
- 10 12. The freeze dried formulation according to any of the preceding claims, wherein the ratio of FSH to LH is within the range of at or about 6:1 to at or about 1:6.
13. The freeze dried formulation according to claim 12, wherein the ratio of FSH to LH is within the range of at or about 4:1 to at or about 1:2.
- 15 14. The freeze dried formulation according to claim 13, wherein the ratio of FSH to LH is within the range of at or about 3:1 to at or about 1:1.
15. The freeze dried formulation according to claim 14, wherein the ratio of FSH to LH is within the range of at or about 2:1 and 1:1.
16. The freeze dried formulation according to any of the preceding claims, further comprising sucrose.
- 20 17. The freeze dried formulation according to any of the preceding claims, further comprising methionine.
18. The freeze dried formulation according to any of the preceding claims, further comprising a phosphate buffer.
- 25 19. The freeze dried formulation according to any of the preceding claims, comprising the following ingredients: rFSH, rLH, Tween 20, sucrose, methionine, a phosphate buffer.
20. The freeze dried formulation according to any of claims 1 to 19, comprising comprising 12.0 µg of recombinant FSH, 3.7 µg of recombinant LH, 30.0 mg of

sucrose, 0.45 mg of $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$, mg 1.11 of $\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$, 0.05 mg of Tween 20 and 0.1 mg of L-methionine.

21. An article of manufacture comprising a first container filled with a freeze dried formulation according to any claims from 1 to 20 and a second container comprising a solvent for reconstitution.
22. An article of manufacture according to claim 21, whereby the second container contains water for reconstitution.
23. A method for manufacturing a freeze dried formulation according to any of claims 1 to 20, comprising the step of forming a mixture of FSH with e LH as well as a Tween 20, and subjecting the mixture to a lyophilisation.